

REMARKS

Claims 1-4, 6-14, and 19-24 stand rejected in the Office Action. Claims 1, 9, and 11 are amended with this Response. Upon entry of the amendments, claims 1-4, 6-14, and 19-24 remain pending.

Support for the amendments to claims 1, 9, and 11 is found in the specification, for example on page 4, lines 9-11. No new matter is added. Applicant respectfully requests entry of the amendments.

Double Patenting Rejection

Claims 1-4, 6-14, and 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 7, 8, and 12 of U.S. Patent 6,117,453. Applicant respectfully traverses the rejection as applied to the amended claims and requests reconsideration.

A double patenting rejection of claims over a patent issued to a common assignee is proper if the subject matter of the claims is obvious over the invention claimed in the patent to such an extent that grant of a patent on the new claims would result in an extension of the inventor's monopoly. The key inquiry is whether the subject matter of the rejected claims is obvious over the claims of the issued patent. For a finding of obviousness to be sustained over a single reference, there must be a motivation elsewhere then in the current application to modify what the reference discloses to arrive at the subject matter of the claims. It is improper to use the current application to provide the motivation.

Claims 1, 9, and 11 have been amended to recite that the coating dissolves in the intestines while withstanding the acidic medium of the stomach and the duodenum. Claims 1, 7-8, and 12 of the '543 patent state merely that a core of a tablet is optionally coated. Applicant

respectfully submits that there is no motivation to modify the subject matter of claims 1, 7-8, and 12 of the '453 patent to arrive at the subject matter of amended claims 1, 9, and 11. Applicant further respectfully submits that the only motivation for so modifying the reference is to be found in the current application. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Applicant notes that claims 21-24 are not rejected under the double patenting doctrine. Claims 21-24 contain the limitation that the coating is soluble at a pH above 5.5. Thus, the pH 5.5 limitation is a non-obvious variant of the claims of the reference. Applicant respectfully submits that the limitation added to claims 1, 9, and 11 is likewise a non-obvious variant, and further distinguishes the subject matter of the current claims from the claims of the reference. For this additional reason, Applicant respectfully requests that the double patenting rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 1-4, 6-14, and 19-24 are rejected under § 103 as unpatentable over the Morella reference of record. Applicant respectfully traverses the rejection as applied to the amended claims and requests reconsideration.

Applicant has amended claims 1, 9, and 11 to recite that the coating dissolves in the intestines but not in the stomach and duodenum. This is consistent with the showing in Dr. Seth's Declaration submitted October 24, 2002. Applicant believes the added limitation is sufficient to distinguish the composition from that disclosed in the Morella reference. For this reason and the reasons discussed in the Supplement Amendment of October 24, 2002, Applicant respectfully submits that amended claims are patentable under § 103 over the Morella reference. Accordingly, Applicant respectfully requests the rejection be withdrawn.

CONCLUSION

For the reasons discussed above, Applicant believes that claims 1-4 , 6-14, and 19-24 as amended are in a condition of allowability and respectfully requests an early notice of allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

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ATTACHMENT FOR CLAIM AMENDMENTS

The following is a marked up version of each amended claim in which underlines indicates insertions and brackets indicate deletions.

1. (Twice Amended) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and
- b) a functional coating consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 0 to 30% by weight of polyethylene glycol and from 30 to 80% of a gastroresistant polymer soluble at a pH above 5.5, and the non-polymer component comprises, based on the weight of the coating, from 10 to 40% of a hydrophilic silicon dioxide[.],

wherein the coating will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum.

9. (Twice Amended) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and 10 to 80% by weight of a gelling agent; and
- b) a coating consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 0 to 30% by weight of polyethylene glycol and from 30 to 80% of uncured poly(meth)acrylic acids, and wherein the non-polymer component comprises from 10 to 40% of a hydrophilic silicon dioxide[.],

wherein the coating will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum.

11. (Twice Amended) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and
- b) a coating consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of, based on the weight of the coating, from 5 to 30% by weight of polyethylene glycol and from 30 to 80% of an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and the non-polymer component comprises from 10 to 40% by weight of a hydrophilic silicon dioxide[.],

wherein the coating will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum.